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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,667	07/20/2001	Stephen D. Kuslich	S85.2-9892	1524

490 7590 08/18/2003

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/18/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	<b>Application No.</b> 09/909,667	<b>Applicant(s)</b> KUSLICH ET AL.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-13, 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (5,571,189).

With respect to claim 1, 15, 17, 19, Kuslich discloses a method of treating a bone abnormality in a body comprising the following steps; exposing an area of bone having an abnormality; as set forth in column 3, line 62; the abnormality is selected from at least one member of the group consisting of: compression fracture of the spine and any combination thereof, forming at least one cavity in the bone, wherein a portion of the at least one cavity defines an opening; as set forth in column 3, line 64, column 8, lines 1-67; inserting an expandable empty fabric bag into the at least one cavity through the opening; as set forth in column 3, lines 60-67; the bag being formed of a fabric wall that includes a plurality of bag openings between about 0.25 to about 5.0 mm in diameter; as set forth in column 7, lines 15-20; the bag defining an interior and having an exterior; as set forth in column 7, lines 8-38; packing the bag through a fill opening with material that will support or promote bone growth through the fabric wall, as set forth in column 7, lines 7-20; the packing causing the bag to expand until the bag and material combination form a self-retaining rigid shape, wherein the exterior of the bag is substantially in contact with the bone of the cavity, the plurality of bag openings

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constructed and arranged to substantially prevent the material from passing from the interior of the bag to the exterior of the bag; as set forth in columns 9-11, lines 1-67 and lines 1-37 respectively.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

With respect to claims 3-13,16,18,20, Kuslich discloses all the method steps, as set forth.

### ***Response to Amendment***

Applicant's arguments filed 6/18/03 have been fully considered but they are not persuasive. Applicant stated that Kuslich'189 did not teach of a method of treating abnormality wherein the abnormality is a compression fracture of the spine and a combination thereof; applicant's attention is directed to Kuslich FIGS. 4,5. Furthermore, although Kuslich did not teach of abnormality selected from at least one member of the group consisting of bone tumors, cysts, a vascular necrosis of the femoral head, tibial plateau fractures, compression fractures of the spine and a combination thereof; however, under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will

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be considered to be anticipated by the prior art device. When the prior art device is the same as the device described in the specification for carrying the claimed method, it can be assumed that the device will inherently perform the claimed method. See *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). See also *In re best*, 562 F.2d 1252, 1255, 195 USPQ430, 433 (CCPA1977).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

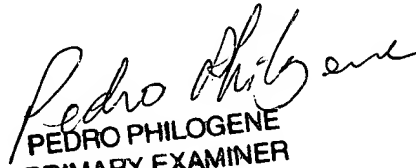
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene  
August 6, 2003

  
PEDRO PHILOGENE  
PRIMARY EXAMINER